

STEVE W. BERMAN (*pro hac vice pending*)
 steve@hbsslaw.com
 HAGENS BERMAN SOBOL SHAPIRO LLP
 1918 Eighth Avenue, Suite 3300
 Seattle, WA 98101
 Telephone: (206) 623-7292
 Facsimile: (206) 623-0594

LEE M. GORDON (SBN 174168)
 lee@hbsslaw.com
 HAGENS BERMAN SOBOL SHAPIRO LLP
 301 N. Lake Avenue, Suite 203
 Pasadena, CA 91101
 Telephone: (213) 330-7150
 Facsimile: (213) 330-7152

*Attorneys for Plaintiff
 and the Proposed Class*

UNITED STATES DISTRICT COURT
 CENTRAL DISTRICT OF CALIFORNIA

Josette Ruhnke, an individual, *et al.*; on
 behalf of herself and all others similarly
 situated,

Plaintiff,

v.

SkinMedica, Inc., a Delaware Corporation,
 and Allergan, Inc., a Delaware
 Corporation;

Defendants.

No. **SACV14 - 00420 DOC (JPRx)**

CLASS ACTION (FRCP 23)

CLASS ACTION COMPLAINT

Demand for Jury Trial

2014 MAR 19 AM 10:40
 CLERK U.S. DISTRICT COURT
 CENTRAL DISTRICT OF CALIF.
 SANTA ANA

FILED

TABLE OF CONTENTS

| | | |
|------|--|----|
| I. | OVERVIEW | 1 |
| II. | PARTIES | 2 |
| III. | JURISDICTION AND VENUE..... | 3 |
| IV. | FACTUAL ALLEGATIONS..... | 4 |
| A. | SkinMedica’s Marketing and Sale of TNS Products..... | 4 |
| B. | Federal and California Food, Drug, and Cosmetics Laws..... | 7 |
| C. | TNS Products Qualify as Drug Products and Require Approval Before Marketing. | 10 |
| D. | TNS Products Are Not Approved by either the FDA or California DPH, and the Labeling Does Not Provide Adequate Safety Warnings..... | 11 |
| E. | Two Growth Factor Products with FDA Approval (Not TNS Products).14 | |
| F. | Defendants Had a Duty to Disclose Safety Concerns about TNS Products and the True Nature of TNS Product Sales..... | 15 |
| G. | Plaintiff and Members of the Class Suffered Injury as a Result of Defendants’ Misconduct. | 17 |
| V. | CLASS ACTION ALLEGATIONS..... | 18 |
| VI. | CAUSES OF ACTION | 22 |

1 Plaintiff Josette Ruhnke (“Plaintiff”) brings this action on behalf of herself and
2 all others similarly situated against SkinMedica, Inc. and Allergan, Inc. (collectively
3 “SkinMedica” or “Defendants”). Plaintiff’s allegations against Defendants are based
4 upon information and belief and upon investigation of Plaintiff’s counsel, except for
5 allegations specifically pertaining to Plaintiff, which are based upon Plaintiff’s
6 personal knowledge.

7 I. OVERVIEW

8 1. As a matter of law and public interest, a health care company should
9 identify and disclose any safety concerns associated with its products before
10 marketing or selling those products to consumers. If the company markets or sells
11 drug products that have not been approved by the relevant government agencies
12 when approval was required, particularly drug products that raise safety concerns,
13 the company should disclose the lack of approval and the illegality of product sales.

14 2. SkinMedica, Inc. is a pharmaceutical company that markets and sells a
15 line of so-called “cosmeceutical” skin care products under the brand name “TNS®”
16 (hereafter, “TNS Products”). Allergan, Inc. is a health care company focused on
17 commercializing pharmaceuticals, biologics, medical devices and over-the-counter
18 consumer products. SkinMedica is an Allergan Company.

19 3. SkinMedica’s TNS Products contain a proprietary mix of “human
20 growth factors” (trademarked as “NouriCel-MD ®”). This SkinMedica growth
21 factor mix was derived from human foreskin tissue.

22 4. Human growth factors are proteins intended to mobilize, stimulate,
23 decrease or otherwise alter the production of cells in vivo. Importantly, they have
24 the ability to initiate mitosis (cell division).

25 5. The human growth factors contained in TNS Products pose significant
26 health risks, including but not limited to the risk of cancer. Indeed, growth factors
27 are believed to contribute to the growth of tumor cells or other abnormalities.

6. TNS Products qualify as drugs (and cosmetics) under both federal laws and parallel state laws governing food, drugs, and cosmetics. Neither the U.S. Food and Drug Administration (“FDA”) nor the California Department of Public Health (“DPH”) has determined that TNS Products are safe, and neither has approved TNS Products for sale. Rather, TNS Products are misbranded under both federal laws and parallel state laws.

7. In marketing and selling TNS Products, SkinMedica materially omits and does not adequately disclose the safety concerns associated with human growth factors contained in TNS Products. Moreover, SkinMedica does not disclose to consumers the lack of government approval for TNS Product sales or the fact that TNS Product sales are illegal in California and the United States.

8. As discussed more fully herein, SkinMedica’s conduct violates:

(i) California’s Business & Professions Code §§ 17200, *et seq.* (the Unfair Competition Laws or “UCL”); (ii) California Civil Code §§ 1750, *et seq.* (the Consumers Legal Remedies Act or “CLRA”); (iii) California’s Business & Professions Code §§ 17500, *et seq.* (the False Advertising Laws or “FAL”); and (iv) California Civil Code §§ 1709-1710 (Deceit).

II. PARTIES

9. Plaintiff Josette Ruhnke is and was at all relevant times a citizen of the State of California, residing in the City of Mission Viejo, California. Plaintiff has purchased and used SkinMedica TNS Products for personal, family, or household purposes, including TNS Essential Serum, which she purchased from the office of Dr. Lorrie Klein at 30201 Golden Lantern, Laguna Niguel, California within the past four years.

10. Plaintiff looked at the product packaging and labeling. If Defendants had properly disclosed the true facts about their TNS Products, Plaintiff either would not have purchased those products and/or she would have paid less for them.

1 11. Defendant SkinMedica, Inc. is a pharmaceutical company
2 headquartered in Carlsbad, California, and incorporated in Delaware. SkinMedica,
3 Inc. is a subsidiary of Allergan, Inc.

4 12. Defendant Allergan, Inc. is a healthcare company headquartered in
5 Irvine, California, and incorporated in Delaware. Allergan, Inc. commercializes
6 pharmaceuticals and other healthcare products. On information and belief, on or
7 about December 19, 2012, Plaintiff alleges that Allergan, Inc. acquired SkinMedica,
8 Inc. along with the assets, liabilities, rights, and responsibilities associated with the
9 SkinMedica TNS Product line. At present, SkinMedica TNS Products are also
10 promoted as Allergan products.

11 13. Plaintiff further alleges upon information and belief that, from and after
12 December 19, 2012, SkinMedica, Inc. was and is an agent of Allergan, Inc. In acting
13 or omitting to act as alleged in this Complaint, SkinMedica, Inc. was conducting
14 business in the course and scope of this agency, and/or the alleged acts or omissions
15 of SkinMedica, Inc. were subsequently ratified and adopted by Allergan, Inc.
16 Accordingly, Allergan, Inc. is liable for the acts and omissions of SkinMedica, Inc.
17 as its agent.

18 **III. JURISDICTION AND VENUE**

19 14. This Court has diversity jurisdiction over this action pursuant to
20 28 U.S.C. § 1332(d) because the amount in controversy for the Class (defined in
21 Part V below) exceeds \$5,000,000, and the Class includes members who are citizens
22 of a different state than Defendants.

23 15. This Court has personal jurisdiction over Plaintiff Josette Ruhnke
24 because she resides in Mission Viejo, California and she submits to the Court's
25 jurisdiction.
26
27
28

1 16. This Court has personal jurisdiction over Defendant Allergan, Inc.
2 because it is headquartered in this Central District of California and it conducts
3 substantial business in this district and throughout the State of California.

4 17. This Court has personal jurisdiction over Defendant SkinMedica, Inc.
5 because it is headquartered in Carlsbad, California, it is a subsidiary of Allergan,
6 Inc., and it conducts substantial business in this district and throughout the State of
7 California.

8 18. Venue is proper in this Court under 28 U.S.C. § 1391(b) because one or
9 more of the Defendants resides in this district, both Defendants reside in this State,
10 Defendants have marketed and sold TNS Products within this district, and a
11 substantial number of the acts and omissions alleged in this Complaint occurred
12 within this district.

13 **IV. FACTUAL ALLEGATIONS**

14 **A. SkinMedica's Marketing and Sale of TNS Products.**

15 19. SkinMedica Inc.'s human growth factor mix was originally developed
16 by a company called Advanced Tissue Sciences ("ATS"). On March 21, 2003,
17 SkinMedica, Inc. acquired the "NouriCel" product line and all of the related assets
18 from ATS. SkinMedica, Inc. began selling NouriCel in 2003 as its "TNS Recovery
19 Complex" skin care product. At present, SkinMedica markets several TNS Products,
20 all of which contain substantially the same proprietary mix of human growth factors
21 contained in the TNS Product line.

22 20. SkinMedica develops, markets, distributes, and sells TNS Products
23 through doctors' offices and retailers in California and nationwide.

24 21. TNS Products include the following: (i) TNS Essential Serum; (ii) TNS
25 Eye Repair; (iii) TNS Ultimate Daily Moisturizer; (iv) TNS Body Lotion; (v) TNS
26 Ceramide Treatment Cream; (vi) TNS Recovery Complex; (vii) TNS Lip Plump
27 System; (viii) TNS Line Refine; (ix) TNS Illuminating Eye Cream; (x) TNS Body
28

1 Mist; (xi) TNS Hydrating Masque; (xii) TNS Hydrafacial Serum; and (xiii) TNS
2 Recovery Complex Body Lotion.

3 22. For purposes of the claims asserted in this action, each TNS Product is
4 substantially similar to each of the other TNS Products insofar as: (a) each TNS
5 Product is a topical skin care product that is developed, marketed, and sold by
6 SkinMedica; (b) each TNS Product contains the same proprietary human growth
7 factor mix (NouriCel-MD®); (c) the labeling and packaging of each TNS Product
8 omits the same material facts about human growth factors; and (d) Plaintiff alleges
9 the same misbranding and nondisclosures about human growth factors, under the
10 same federal law and parallel state law requirements, for the same reasons with
11 respect to each TNS Product.

12 23. SkinMedica promotes TNS Products as “cosmeceuticals” containing a
13 mix of endogenous “growth factors” for skin rejuvenation. The term
14 “cosmeceutical” conveys that a product is both a cosmetic and pharmaceutical. In
15 SkinMedica, Inc.’s 2004 IPO summary listed on NASDAQ, the company publicized:

16 We are a specialty pharmaceutical company focused on
17 developing, acquiring and commercializing products that
18 treat dermatologic conditions and diseases and improve the
19 appearance of skin. Through our own sales force, we
20 market and sell primarily to dermatologists both
21 prescription pharmaceutical products and physician-
22 dispensed, non-prescription skin care products, which we
23 refer to as cosmeceuticals for marketing purposes.

24 * * *

25 Our cosmeceutical products are physician-dispensed, non-
26 prescription products designed to enhance skin appearance,
27 reduce signs of aging and provide other skin care benefits.

1 Our leading cosmeceutical product line is Tissue Nutrient
2 Solution, or TNS, which contains a biotechnology-derived,
3 naturally occurring mix of growth factors and other key
4 ingredients that, when applied topically, may improve the
5 appearance of skin.

6 24. Each TNS Product lists “Human Fibroblast Conditioned Media” as an
7 active ingredient, and each TNS Product contains the same human growth factor
8 mix—NouriCel-MD. The labeling and packaging of each TNS Product, however,
9 omits the same material facts about NouriCel-MD (as discussed more fully below).

10 25. SkinMedica’s Product Guide has described TNS Products as “skin
11 rejuvenation” products vital to the anti-aging process that works with the skin’s
12 “natural cellular restructuring process.” SkinMedica describes growth factors in the
13 Product Guide as proteins that “regulate cellular growth and the activity of skin
14 cells.” SkinMedica further describes TNS®, a Tissue Nutrient Solution, as “a
15 combination of growth factors and other naturally occurring elements that are crucial
16 to the regeneration of healthy skin.” A snapshot of a relevant portion of
17 SkinMedica’ 2011 Product Guide follows:

SKIN REJUVENATION

This vital step in the anti-aging process works with your skin's natural cellular restructuring process to reduce the appearance of fine lines and wrinkles, diminish age spots, and improve skin texture and elasticity.

WHAT ARE GROWTH FACTORS AND HOW DO THEY WORK?

- Growth factors are proteins that regulate cellular growth and the activity of skin cells.
- There are different growth factors present in skin as a physiologically balanced combination to maintain a healthy skin structure.
- Through normal aging, the production and level of growth factors decreases, resulting in impaired skin repair, wrinkles and fine lines.

WHAT IS TNS*?

Tissue Nutrient Solution (TNS) is a combination of growth factors and other naturally occurring elements that are crucial to the regeneration of healthy skin.

TNS RECOVERY COMPLEX*
(Applied twice daily)

Female, Age 54
Baseline

Female, Age 63
Baseline

TNS ESSENTIAL SERUM*
(Applied twice daily)

Female, Age 54
Baseline

Age 40

TNS RECOVERY COMPLEX*

This unparalleled gel is the first and only patented anti-aging treatment using the highest level of a combination of growth factors clinically proven to improve the appearance of fine lines and wrinkles, skin tone, texture and elasticity.
AM/PM

ALL SKIN TYPES

Figure 1

26. In the same Product Guide, SkinMedica also describes the flagship TNS Recovery Complex® product as the first and only patented anti-aging treatment using a combination of “growth factors clinically proven to improve the appearance of fine lines and wrinkles, skin tone, texture, and elasticity.”

B. Federal and California Food, Drug, and Cosmetics Laws.

27. The federal Food, Drug, and Cosmetics Act (“FDCA”) (21 U.S.C. §§ 301 *et. seq.*) defines drugs to mean, in relevant part [C]: “articles (other than food) intended to affect the structure or any function of the body of man or other animals” [21 § U.S.C. 321(g)(1)]. Likewise, California’s Sherman Food, Drug, and Cosmetics Law (“Sherman FD&C”) (California’s Health & Safety Code §§ 109875 *et. seq.*) provides in pertinent part that “‘Drug’ means any of the following: . . . (c) Any article

1 other than food, that is used or intended to affect the structure or any function of the
2 body of human beings or any other animal.” [Cal. Health & Safety Code § 109925]

3 28. Notably, there is no separate category for “cosmeceuticals” under the
4 FDCA or Sherman FD&C. Products that qualify both as drugs and cosmetics must
5 comply with regulations both for drugs and cosmetics.

6 29. The regulatory scheme for drugs (including drug products marketed as
7 cosmeceuticals) varies based on whether the product is a prescription only product or
8 an Over-The-Counter (“OTC”) product. Under the federal scheme, drug
9 manufacturers generally must file NDAs (New Drug Applications) with the FDA in
10 order to start the regulatory process.

11 30. When a drug product qualifies as a “biologic” under FDA regulations,
12 the manufacturer (or other responsible party) must file a Biologics License
13 Application (“BLA”) to start the process of obtaining FDA approval. Biologics are
14 regulated like prescription drugs. The BLA is a request for permission to introduce,
15 or deliver for introduction, a biologic product into interstate commerce. BLA
16 requirements include, among other things, pre-clinical studies, clinical studies, and
17 labeling requirements.¹

18 31. Under the FDCA, non-biologic OTC drug products that conform to
19 “monographs” for particular drug categories could be marketed under federal law
20 without an NDA, but they still would need to conform to the monographs in the
21 Code of Federal Regulations, and the FDA has stringent labeling requirements for
22 such drugs. In addition to providing specific and mandated information about the
23 contents of OTC drugs, the FDCA requires labeling disclosures about dosages,
24 warnings, and allergic reaction alerts (among other required disclosures).

25
26
27 ¹ “Biologics” include proteins derived from human sources and isolated through
28 biotechnology methods.

1 32. The introduction or delivery of “misbranded” drug products in interstate
2 commerce is prohibited under the FDCA, as is the misbranding of any drug product.
3 [21 U.S.C. § 331] Under the FDCA, a drug product will be deemed “misbranded”
4 for the following reasons (among others): if its labeling is false or misleading in any
5 particular (such as by failing to disclose material facts about the drug product to
6 consumers); if any required wording is not prominently displayed and clearly stated
7 on the label; if the labeling does not bear adequate warnings against unsafe dosage,
8 or methods, or duration of administration or application; if it is dangerous to health
9 when used in the dosage or manner or with the frequency or duration prescribed,
10 recommended or suggested in the labeling; or if there is a failure or refusal to comply
11 with any requirement prescribed under the FDCA. [21 U.S.C. § 352]

12 33. California’s Sherman FD&C Law parallels the FDCA in material part
13 and adopts all nonprescription drug regulations and NDA regulations pursuant to the
14 federal FDCA as state regulations.

15 34. Under California’s Sherman FD&C Law, no one may sell any new drug
16 unless it has an approved NDA or BLA under federal law or unless the California
17 DPH has approved a new drug application. In addition, no person shall manufacture
18 any drug in California unless he or she has a valid license from the California DPH.

19 35. The Sherman FD&C Law further provides that any drug that, because of
20 the potentiality for harmful effect is not safe for use except under the supervision of a
21 licensed practitioner requires a prescription and a product label warning that sale
22 requires a prescription.

23 36. Furthermore, the drug product labeling and packaging must conform to
24 specific state regulations and the labeling must bear adequate warnings against
25 unsafe dosage or methods or duration of administration or application. All
26 advertising materials must include a summary of side effects and contraindications.
27
28

37. Under the Sherman FD&C Law, much like under the federal FDCA, it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug that is misbranded, or to misbrand any drug. [Cal. Health & Safety Code §§ 111440, 111445] A drug is “misbranded” under the Sherman FD&C Law if it fails to comply with any of the above-described regulations or if its labeling is otherwise false or misleading in any particular (such as by failing to disclose material facts about the drug product to consumers).

C. TNS Products Qualify as Drug Products and Require Approval Before Marketing.

38. TNS Products are articles (other than food) intended to affect the structure or any function of the human body, namely the skin. “Growth factors are proteins that regulate cellular growth, proliferation and differentiation under controlled conditions” and they affect “skin structure and function.”² Indeed, TNS Products are designed to affect the skin’s structure and function by inducing cell division and replication and stimulating skin cell production.³ TNS Products do not strictly mask, cleanse, or moisturize the skin (as do cosmetics)—TNS Products use human growth factors (NouriCel-MD®) to affect cell biology. Furthermore, the NouriCel-MD in TNS Products is designed to promote the formation of collagen and/or elastic fibres in the skin. For each of these reasons, TNS Products qualify as drugs both under the FDCA and the Sherman FD&C, and regulations thereunder. As such, SkinMedica required FDA approval and/or California DPH approval before it could lawfully make, market, and sell TNS Products.

² See Role of Growth Factors in Skin Creams, Facts About the Skin from DermNet New Zealand Trust (available online at: www.dermnetnz.org/treatments/growth-factor-creams.html).

³ Skin care products that are designed to regenerate skin cells have been recognized as drug products by the FDA. See, e.g., <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm>.

1 39. TNS Products are also “biologics” insofar as they contain proteins
2 (human growth factors) derived from human foreskin tissue and isolated through
3 biotechnology methods.

4 40. SkinMedica’s manufacture, marketing, and sale of TNS Products violate
5 California’s Sherman FD&C Law (California’s Health & Safety Code §§ 109875 *et*.
6 *seq.*) and constitutes misbranding thereunder (and corresponding provisions of
7 federal law). The labeling and packaging fail to disclose important and mandatory
8 information about use of TNS Products (and the human growth factors contained
9 therein). Without limitation, TNS Products are misbranded as follows: (i) under
10 § 111330, because the product labeling is misleading insofar as it fails to disclose all
11 significant safety concerns; (ii) under § 111335, because the product labeling and
12 packaging do not conform to the requirements of Chapter 4 (commencing with
13 § 110290); (iii) under § 111360, because SkinMedica fails to include in all
14 advertising materials a summary of all side effects and contraindications; (iv) under
15 § 111375, because the product labeling does not bear adequate warnings as to unsafe
16 dosages or methods or duration of administration or application; and/or (v) under
17 § 111400, because it may be dangerous to health when used in the suggested
18 frequency, duration, or dosage.

19 41. Moreover, SkinMedica’s manufacture, marketing, and sale of TNS
20 Products are unlawful under the Sherman FD&C Law because the products are sold
21 without an approved new drug application or BLA [California’s Health & Safety
22 Code § 111550].

23 **D. TNS Products Are Not Approved by either the FDA or California DPH,**
24 **and the Labeling Does Not Provide Adequate Safety Warnings.**

25 42. Although TNS Products qualify as drugs (and biologics) under federal
26 and state laws alike, they are not approved either by the FDA or California DPH.
27
28

1 43. SkinMedica markets TNS Products as if they did not require
2 government approval, when in fact the products do require government approval.

3 44. On its website, SkinMedica maintains that most of its products
4 (including TNS Products) are intended to meet the FDA's definition of cosmetic
5 products but are not intended to be drug products.⁴ Importantly, however, TNS
6 Products are intended to use human growth factors (originally derived from human
7 foreskin tissue) to affect the structure and function of the skin through cell division,
8 multiplication, and regeneration of skin tissue. Consequently, TNS Products meet
9 the definition of "drugs" (and biologics) under both federal laws and parallel state
10 laws.

11 45. SkinMedica wrongly pronounces that TNS Products do not require FDA
12 approval. Because TNS Products are drug products being sold without FDA
13 approval, and because SkinMedica does not provide mandatory and important
14 product labeling information (as required by the FDA and California DPH for such
15 products), they are misbranded under both the federal FDCA and parallel provisions
16 of California's Sherman FD&C.

17 46. In particular, SkinMedica's TNS Products require—but do not
18 provide—disclosures of significant health risks associated with human growth
19 factors. That is to say, SkinMedica markets and sells TNS Products without warning
20 consumers that the NouriCel-MD in TNS Products poses significant health risks,
21 including but not limited to the risk of cancer from unintended cell growth or other
22 abnormalities.

23 47. According to Allergan, all safety concerns associated with SkinMedica
24 TNS Products are described on package inserts that accompany the products.

25
26
27 ⁴ SkinMedica's own website, for example, includes such a representation at the
28 bottom of the home page. *See* <http://www.skinmedica.com>.

1 48. In reality, the labeling and package inserts that accompany SkinMedica
 2 TNS Products do not describe the safety concerns at issue. The available scientific
 3 literature regarding human growth factors indicates that growth factors (including
 4 those in TNS) raise serious safety concerns, including tumor growth and adverse
 5 reactions (such as allergic reactions, eye issues, and rashes). Growth factors have
 6 known carcinogenic potential because they literally cause cells to grow, and every
 7 growth factor has certain tumor types that secrete the specific growth factor. TNS
 8 Products, however, do not describe these safety concerns.

9 49. For example, TNS Products contain a formula that purportedly blends
 10 over 110 growth factors, including KGF-1. Substantial scientific evidence shows
 11 that KGF-1 contributes to the growth of a number of cancers (e.g., breast cancer).⁵
 12 The labeling and package inserts that accompany SkinMedica TNS Products do not
 13 identify any cancer risks due to the human growth factors contained in the products.

14 50. “Most of the research on human growth factors for skin has looked
 15 primarily at the issue of wound healing, and at short-term use. Much remains
 16 unknown at this time, especially in terms of long-term risk or stability, when growth
 17 factors are used in cosmetics and applied to skin. Well-controlled clinical studies are
 18 lacking.”⁶ Wound healing treatments using human growth factors have a black box
 19 warning and are approved by the FDA. The dearth of well-controlled clinical studies
 20 is particularly dangerous in this context, since skin care products get used repeatedly
 21 and often over extended periods of time.

22 51. Dr. Fitzpatrick is the doctor credited with creating NouriCel-MD®, the
 23 key component of TNS Products. In a 2008 report written by Dr. Fitzpatrick, he
 24 acknowledged: “More double-blind and controlled studies are needed to confirm the

25 ⁵ See Journal of the National Cancer Institute, Vol. 98, No. 12, 2006.

26 ⁶ See Role of Growth Factors in Skin Creams, Facts About the Skin from
 27 DermNet New Zealand Trust (available online at:
 28 www.dermnetnz.org/treatments/growth-factor-creams.html).

1 preliminary clinical effects of growth factor products, and more controls on product
2 quality and stability need to be established.”⁷ No such double-blind and controlled
3 studies have been reported and do not appear to be recognized by the FDA or
4 California DPH.

5 **E. Two Growth Factor Products with FDA Approval (Not TNS Products).**

6 52. Plaintiff knows of only two FDA-approved products available to the
7 public that contain human growth factors. Both products provide prominent health
8 warnings on their labels addressing significant health risks. Both products are
9 authorized only for the treatment of specific and limited severe medical conditions.

10 53. There is one FDA-approved topical formula containing human growth
11 factors: REGRANEX® Gel (Becaplermin). Regranex was approved by the FDA
12 under a BLA, because Regranex contains a recombinant human platelet-derived
13 growth factor (rhPDGF-BB) for topical administration. Accordingly, growth factors
14 derived from human cells already have been recognized by the FDA as biologics.

15 54. Regranex, which is used for diabetic foot ulcers, includes a black box
16 warning that describes a fivefold increase in deaths from cancer when three or more
17 tubes are used. The Regranex label warns that the product contains “a recombinant
18 human platelet-derived growth factor, which promotes cellular proliferation and
19 angiogenesis,” and further warns that the benefits and risks of the growth factor
20 treatment should be carefully evaluated. By contrast, the labeling and package
21 inserts that accompany SkinMedica TNS Products do not provide similar safety
22 warnings.

23 55. There is one FDA-approved intravenous drug containing growth factors:
24 Kepivance, which was approved for treatment of severe oral mucositis. According
25 to its label, “Kepivance has been shown to enhance the growth of human epithelial
26 tumor cell lines in vitro” and poses other risks such as “fetal harm.” By contrast, the

27
28 ⁷ See <http://www.ncbi.nlm.nih.gov/pubmed/18045360>.

1 labeling and packaging of SkinMedica TNS Products do not provide similar safety
2 warnings.

3 **F. Defendants Had a Duty to Disclose Safety Concerns about TNS Products**
4 **and the True Nature of TNS Product Sales.**

5 56. Defendants had a duty to disclose: (a) safety concerns posed by the
6 human growth factor mix in TNS Products; (b) the lack of government approval of
7 TNS Products as drug products; and (c) the illegality of TNS Product sales.

8 57. At all relevant times, Defendants had superior and exclusive knowledge
9 of material facts about the health risks and related safety concerns posed by the
10 human growth factor mix in TNS Products, and about the lack of government
11 approval and illegality of TNS Product sales. Such facts were not known or
12 reasonably accessible to Plaintiff. Plaintiff is informed and believes that Defendants
13 had superior and exclusive knowledge of these material facts through its product
14 testing and internal legal reviews (and Allergan's due diligence review in connection
15 with the acquisition of SkinMedica, Inc.) that would have revealed the safety
16 concerns associated with TNS Products and the lack of government approvals and
17 illegality of TNS Product sales.

18 58. Plaintiff is further informed and believes that Defendants were aware of
19 consumer complaints and scholarly research about safety concerns and adverse
20 reactions associated with human growth factors (e.g., NouriCel-MD contained in
21 TNS Products), which information was reasonably known to Defendants at all
22 relevant times.

23 59. Defendants were familiar with the requisite federal regulatory scheme
24 having sought approval for a variety of drug products other than TNS Products.
25 Plaintiff is informed and believes that, through consumer complaints, competitors,
26 and/or market research, Defendants were aware that they were marketing and selling
27
28

1 TNS Products without proper FDA approval, but Defendants continued to market
2 and sell such products anyway.

3 60. Defendants actively concealed material facts from Plaintiff and
4 members of the Class about safety concerns associated with TNS Products, the true
5 regulatory status of TNS Products, and the illegality of TNS Product sales.
6 Defendants also ignored reports of adverse reactions from human growth factors.

7 61. At the same time, Defendants were intimately aware of the true nature
8 of NouriCel-MD in TNS Products, including that it affects the structure and/or
9 function of the skin, and thus knew or reasonably should have known that TNS
10 Products were drug products within the governing federal and state law definitions.
11 Nonetheless, Defendants affirmatively represented to consumers that TNS Products
12 were considered cosmetics but not drug products. Defendants also wrongly
13 informed consumers that TNS Product packaging disclosed all relevant safety
14 information. In this manner, Defendants actively concealed the safety concerns,
15 approval status, and illegality associated with TNS Product sales.

16 62. By marketing and selling TNS Products, Defendants effectively
17 represented that the products were approved by the FDA or California DPH, and that
18 they were legally saleable, when they were not. Such representations were
19 misleading absent full disclosure of material facts about unevaluated safety concerns,
20 the true regulatory status of TNS Products, and the illegality of such product sales.

21 63. Reasonable consumers would consider the omitted facts to be important
22 in determining whether or not to purchase TNS Products, namely the omitted facts
23 regarding: safety concerns, the approval status, and illegality of sales. To be sure,
24 nondisclosures about such facts are generally recognized to be material omissions.
25
26
27
28

G. Plaintiff and Members of the Class Suffered Injury as a Result of Defendants' Misconduct.

64. SkinMedica's conduct violates California's UCL, CLRA, FAL, and civil laws against deceit. In particular, this class action seeks to remedy SkinMedica's unlawful, unfair, and deceptive marketing and sale of misbranded drug products without full and adequate disclosure of: (a) significant safety concerns, (b) the lack of government approval, and (c) the illegality of product sales. SkinMedica's conduct violates California's consumer protection laws and injures consumers in California and nationwide.

65. At all relevant times, SkinMedica has been under a duty to Plaintiff and other similarly situated consumers to identify and disclose the true health risks and related safety concerns associated with human growth factors contained in TNS Products. At the same time, SkinMedica has been under a duty to disclose to consumers the lack of government approval and the illegality of TNS Product sales.

66. For at least the past four years, SkinMedica has failed to disclose the significant safety concerns associated with TNS Products, the lack of government approval, and the illegality of TNS Product sales. Plaintiff is informed and believes that Defendants have not conducted adequate safety studies on TNS Products.

67. Upon information and belief, at least thousands of consumers have been victims of SkinMedica's unlawful, unfair, and deceptive marketing and sale of TNS Products. SkinMedica knows or reasonably should know that the marketing and sale of TNS Products was and is unlawful, unfair, and deceptive.

68. The true facts about safety concerns, lack of government approval, and illegality of TNS Product sales would be material to a reasonable consumer. Therefore, consumer reliance upon SkinMedica's material omissions can and should be presumed as a matter of law.

1 69. Plaintiff purchased TNS Products while unaware of significant safety
2 concerns, the lack of government approval, or the illegality of product sales.

3 70. Plaintiff and members of the Class lost money as a result of
4 SkinMedica's material omissions regarding the health risks and legal status of TNS
5 Products.

6 71. Based on the material omissions described herein, Plaintiff and
7 members of the Class were induced to and did purchase SkinMedica TNS Products
8 instead of saving their money or purchasing competing skin care products.

9 72. Plaintiff and members of the Class altered their position to their
10 detriment and suffered injuries that include payment of the purchase price for TNS
11 Products and/or payment of price premiums for such products.

12 73. At the time Plaintiff purchased TNS Products, Plaintiff relied upon
13 SkinMedica's material omissions of fact regarding significant safety concerns, the
14 lack of government approval, and the illegality of product sales. Plaintiff and other
15 similarly situated consumers were likely to be misled, and they reasonably and
16 justifiably relied to their detriment on SkinMedica's omissions of material facts.

17 74. If SkinMedica had disclosed the truth about significant safety concerns,
18 the lack of government approval, and the illegality of product sales, Plaintiff would
19 not have purchased TNS Products or paid as much for them.

20 75. As a result of the alleged misconduct, SkinMedica has generated
21 substantial revenues from the sale of TNS Products.

22 76. Plaintiff, individually and on behalf of all others similarly situated,
23 seeks damages, restitution and injunctive relief to put an end to SkinMedica's unfair
24 business practices.

25 **V. CLASS ACTION ALLEGATIONS**

26 77. Plaintiff seeks certification of a Class defined as follows:

27 All consumers nationwide who: (i) purchased any TNS
28 Product (ii) for personal, family, or household purposes

(iii) at any time during the four year period preceding the filing of the original complaint ("The Class"). Excluded from the Class are Defendants; the officers, directors or employees of Defendants; any entity in which Defendants have a controlling interest; and any affiliate, legal representative, heir or assign of Defendants. Also, excluded from the Class are any federal, state or local governmental entities, any judicial officer presiding over this action and the members of his/her immediate family and judicial staff, and any juror assigned to this action.

78. Plaintiff does not assert any personal injury claim in this action as a result of using Defendants' TNS Products.

79. Plaintiff does not know the exact number of Class members at the present time. However, due to the nature of the trade and commerce involved, there appear to be thousands of Class members such that joinder of all Class members is impracticable.

80. The Class is ascertainable and notice can be provided through techniques similar to those customarily used in other consumer fraud cases and complex class actions, and through SkinMedica's business records.

81. There are questions of law and fact common to the Class. Defendants' unlawful omissions similarly impact Class members, all of who purchased one or more of SkinMedica's TNS Products.

82. Plaintiff asserts claims that are typical of the Class. Plaintiff and all Class members have been subjected to the same wrongful conduct because they all have purchased SkinMedica's misbranded TNS Products that contained human growth factors (NouriCel-MD), that lacked regulatory approval from the FDA and California DHS, and that failed to provide adequate warnings of health risks. As a result, and like other members of the Class, Plaintiff purchased and paid an amount for TNS Products which she otherwise would not have paid.

1 83. Plaintiff will fairly and adequately represent and protect the interests of
2 the Class. Plaintiff is represented by counsel competent and experienced in both
3 consumer protection and class action litigation.

4 84. Class certification is appropriate because Defendants have acted on
5 grounds that apply generally to the Class, so that final injunctive relief or
6 corresponding declaratory relief is appropriate respecting the Class as a whole.

7 85. Class certification is also appropriate because common questions of law
8 and fact substantially predominate over any questions that may affect only individual
9 members of the Class, including, *inter alia*, the following:

- 10 a. Whether TNS Products qualify as drug products
11 under federal and parallel state laws governing food,
 drugs, and cosmetics;
- 12 b. Whether TNS Products are misbranded under federal
13 and parallel state laws governing food, drugs, and
 cosmetics;
- 14 c. Whether the manufacture, marketing, or sale of TNS
15 Products are unlawful under federal and parallel
 state laws governing food, drugs, and cosmetics;
- 16 d. Whether Defendants had a duty to disclose material
17 facts regarding safety concerns associated with TNS
 Products, or the lack of government approvals, or the
18 illegality of TNS Product sales;
- 19 e. Whether Defendants failed to disclose material facts
20 regarding safety concerns associated with TNS
 Products, such as the potential for uncontrolled cell
21 growth and the absence of well-controlled safety
 studies;
- 22 f. Whether Defendants failed to disclose material facts
23 regarding the lack of government approval of TNS
 Products;
- 24 g. Whether Defendants failed to disclose material facts
25 regarding the illegality of TNS Product sales;
- 26 h. Whether Defendants' nondisclosures would be
27 material to a reasonable consumer;
- 28 i. Whether Defendants' nondisclosures constitute an
 unlawful business practice in violation of the UCL;

- j. Whether Defendants' nondisclosures constitute an unfair business practice in violation of the UCL;
- k. Whether Defendants' nondisclosures were likely to deceive a reasonable consumer in violation of the UCL, CLRA, or FAL;
- l. Whether Defendants knowingly or willfully failed to disclose significant safety concerns associated with TNS Products;
- m. Whether Defendants knowingly or willfully failed to disclose material facts regarding the lack of government approval of TNS Products;
- n. Whether Defendants knowingly or willfully failed to disclose material facts regarding the illegality of TNS Product sales;
- o. Whether the challenged practices harmed Plaintiff and members of the Class; and
- p. Whether Plaintiff and members of the Class are entitled to damages, restitution, equitable relief, and/or injunctive relief.

86. A class action is superior to other available methods for the fair and efficient adjudication of this controversy, since joinder of all the individual Class members is impracticable. Furthermore, because the restitution and/or damages suffered, and continue to be suffered, by each individual Class member may be relatively small, the expense and burden of individual litigation would make it very difficult or impossible for individual Class members to redress the wrongs done to each of them individually and the burden imposed on the judicial system would be enormous.

87. The prosecution of separate actions by the individual Class members would create a risk of inconsistent or varying adjudications, which would establish incompatible standards of conduct for Defendants. In contrast, the conduct of this action as a class action presents far fewer management difficulties, conserves judicial resources and the parties' resources, and protects the rights of each Class member.

VI. CAUSES OF ACTION

FIRST CAUSE OF ACTION

**VIOLATION OF THE CALIFORNIA UNFAIR COMPETITION LAW
(CAL. BUS. & PROF. CODE § 17200, *et seq.*)**

88. Plaintiffs reallege and incorporate by reference all paragraphs alleged herein.

89. Cal. Bus. & Prof. Code § 17200 prohibits any “unlawful, unfair, or fraudulent business act or practice.” Defendants have engaged in unlawful, and unfair, and fraudulent business acts and practices in violation of the UCL.

90. Defendants have violated the unlawful prong by virtue of their violations of the Sherman Food Drug & Cosmetics Laws, California’s Health & Safety Code §§ 111330 *et seq.*, and selling misbranded drug products thereunder.

91. In addition, Defendants have violated the unlawful prong by virtue of their violations of the CLRA, the FAL, and Cal. Civil Code §§ 1709-1710.

92. Defendants have violated the unfair prong of section 17200 because the acts and practices set forth in the Complaint—including the omission of product safety concerns—offend established public policy. The challenged conduct is substantially injurious to consumers. The harm that these acts and practices cause to consumers greatly outweighs any benefits associated with them. Reasonable consumers are not in a position to know and understand the safety concerns posed by the TNS Products being made, marketed, and/or sold by Defendants.

93. Defendants’ conduct also impairs competition within the market for skin care products, and stops Plaintiff and Class members from making fully informed decisions about the kind of skin care products to purchase or the price to pay for such products.

94. Defendants have violated the fraudulent prong of section 17200 because their material omissions about safety concerns associated with TNS Products were

likely to deceive a reasonable consumer and the true facts would be material to a reasonable consumer. Moreover, Defendants material omissions about the lack of government approval of TNS Products, and/or the illegality of TNS product sales, were likely to deceive a reasonable consumer, and the true facts would be material to a reasonable consumer.

95. Plaintiff has suffered injury in fact, including the loss of money, as a result of Defendants' unlawful, unfair, and/or deceptive practices. As set forth more fully above, in purchasing TNS Products, Plaintiff relied on Defendants to make complete disclosures of all material information about her purchase. Had she known about the safety concerns associated with TNS Products (including but not limited to an increased risk of cancer), or that the products were misbranded, lacked required government approvals, and were legally unsaleable, she would not have purchased those TNS Products or she would have paid less for them.

96. All of the wrongful conduct alleged herein occurred, and continues to occur, in the conduct of SkinMedica's business. Defendants' wrongful conduct is part of a general practice that is still being perpetuated and repeated throughout the State of California and nationwide.

97. Plaintiff requests that this Court enter such orders or judgments as may be necessary to enjoin Defendants from continuing its unlawful, unfair, and deceptive business practices, to restore to Plaintiff and members of the Class any money that Defendants acquired by unfair competition (as provided in Cal. Bus. & Prof. Code § 17203), and to provide such other relief as set forth below.

SECOND CAUSE OF ACTION

VIOLATIONS OF THE CONSUMERS LEGAL REMEDIES ACT (CAL. CIV. CODE § 1750, *et seq.*)

98. Plaintiff realleges and incorporates by reference all paragraphs alleged herein.

1 99. Defendants are “persons” under Cal. Civ. Code § 1761(c).

2 100. Plaintiff is a “consumer,” as defined by Cal. Civ. Code § 1761(d), who
3 purchased TNS Products, which are goods that were made, marketed, and/or sold by
4 Defendants.

5 101. Cal. Civ. Code § 1770(a)(2) prohibits “[m]isrepresenting the source,
6 sponsorship, approval, or certification of goods or services.” Defendants violated
7 this provision by marketing and selling misbranded drug products, which required
8 government approval for sale, but which did not have it. The sale of each TNS
9 Product was a misrepresentation that the product was approved by the FDA and/or
10 California DPH.

11 102. Cal. Civ. Code § 1770(a)(5) prohibits “[r]epresenting that goods or
12 services have sponsorship, approval, characteristics, ingredients, uses, benefits, or
13 quantities which they do not have....” Defendants violated this provision by
14 marketing and selling misbranded drug products that posed safety concerns. The
15 sale of each TNS Product misrepresented that the product was free of undisclosed
16 safety concerns. In addition, the sale of each TNS Product misrepresented that the
17 product had all necessary government approvals and was otherwise legally offered
18 for sale.

19 103. Cal. Civ. Code § 1770(a)(7) prohibits “[r]epresenting that goods or
20 services are of a particular standard, quality, or grade, or that goods are of a
21 particular style or model, if they are of another.” Defendants violated this provision
22 by marketing and selling misbranded drug products that posed safety concerns. The
23 sale of each TNS Product misrepresented that the product was free of undisclosed
24 safety concerns. In addition, the sale of each TNS Product misrepresented that the
25 product had all necessary government approvals and was otherwise legally offered
26 for sale.

1 104. The CLRA (including §§ 1770(a) (2), (5), (7)) supports claims for
2 omissions of material fact that Defendants were obligated to disclose. In this case,
3 Defendants were obligated to disclose—but failed to disclose—the known safety
4 concerns associated with human growth factors contained in TNS Products, the lack
5 of government approvals of TNS Products, and the illegality of TNS Product sales.

6 105. Plaintiff and the Class lost money and were damaged as a result of
7 SkinMedica's violations of the CLRA because: (a) they purchased TNS Products
8 due to the material omissions about the products' safety concerns, approval status,
9 and saleability; and (b) they would not have purchased TNS Products on the same
10 terms if the true facts had been known. Absent these material omissions, Plaintiff
11 and the Class would not have purchased TNS Products at all or they would have paid
12 less for them.

13 106. As a result of these violations, Defendants have caused and continue to
14 cause damage to Plaintiff and members of the Class and, if not stopped, will continue
15 to harm them.

16 107. In accordance with Cal. Civ. Code § 1780(a), Plaintiffs and members of
17 the Class seek injunctive and equitable relief for SkinMedica's violations of the
18 CLRA.

19 108. Although Plaintiff does not seek to recover damages under the CLRA in
20 this initial Complaint, after mailing appropriate notice and demand in accordance
21 with Civil Code § 1782(a) & (d), Plaintiff will subsequently amend this Complaint to
22 also include a request for compensatory and punitive damages.

23 109. Plaintiffs include an affidavit with this Complaint reflecting that venue
24 in this District is proper, to the extent such an affidavit is required by Cal. Civ. Code
25 § 1780(d) in federal court.

THIRD CAUSE OF ACTION

**VIOLATIONS OF THE FALSE ADVERTISING LAW
(CAL. BUS. & PROF CODE §§ 17500, *et seq.*)**

110. Plaintiff realleges and incorporates by reference all paragraphs alleged herein.

111. California Business & Professions Code §§ 17500, *et seq.* (the “FAL”) broadly proscribes deceptive advertising in this State. Section 17500 makes it unlawful for any corporation intending to sell products or perform services to make any statement in advertising those products or services concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading, or not to sell those products or services as advertised at the price stated therein, or as so advertised.

112. When the seller has a duty to disclose material facts about a product, the sale of the product to consumers without disclosure of such material facts runs afoul of the FAL.

113. SkinMedica markets and sells the TNS Product line as if the products are free of significant safety concerns, when in fact, they are not. SkinMedica effectively misrepresents the health risks posed by human growth factors and the failure to conduct adequate safety evaluations thereof.

114. SkinMedica also markets and sells the TNS Product line as if the products have all necessary government approvals and are legally offered for sale, when in fact, they do not have such approvals and are misbranded and sold illegally.

115. Section 17535 effectively provides that the Court may enjoin any corporation or other person who violates the FAL, and may make such orders or judgments as may be necessary to prevent the use of such practices, or which may be necessary to restore to any person in interest any money or property which may have

1 been acquired by means of such practices. An FAL claim may be prosecuted by any
 2 person who has suffered injury in fact and has lost money or property as a result of a
 3 violation of the FAL. The action may be prosecuted on a representative basis when it
 4 meets the traditional class action requirements.

5 116. Plaintiff and the Class have suffered injury in fact and lost money or
 6 property as a result of SkinMedica's violations of the FAL because: (a) they
 7 purchased TNS Products due to the material omissions about safety concerns, the
 8 lack of government approvals, and the illegality of product sales; and (b) they would
 9 not have purchased TNS Products on the same terms if the true facts had been
 10 known. Absent the material omissions, Plaintiff and the Class would not have
 11 purchased TNS Products at all or they would have paid less for them.

12 117. As a result of these violations, Defendants have caused and continue to
 13 cause damage to Plaintiff and members of the Class and, if not stopped, will continue
 14 to harm them.

15 118. Plaintiff and members of the Class request that this Court enjoin
 16 Defendants from continuing to market and sell TNS Products without required
 17 government approvals and disclosure of known safety concerns.

18 119. In addition, Plaintiff and members of the Class request that this Court
 19 enter such orders or judgments as may be necessary to restore to any person in
 20 interest any money which may have been acquired by means of such material
 21 omissions and deceptive marketing and selling of TNS Products to consumers.

22 **FOURTH CAUSE OF ACTION**

23 **DECEIT (CAL CIV. CODE §§ 1709-1710)**

24 120. Plaintiffs reallege and incorporate by reference all paragraphs alleged
 25 herein.
 26
 27
 28

1 121. Under California Civil Code § 1709: “One who willfully deceives
2 another with intent to induce him to alter his position to his injury or risk, is liable
3 for any damage which he thereby suffers.”

4 122. Under California Civil Code § 1710, Deceit includes (among other
5 things): “[i] The suggestion, as a fact, of that which is not true, by one who does not
6 believe it to be true; or [ii] the suppression of a fact, by one who is bound to disclose
7 it, or who gives information of other facts which are likely to mislead for want of
8 communication of that fact.”

9 123. By marketing and selling TNS Products, Defendants willfully suggest
10 that TNS Products do not pose significant safety concerns, comply with all required
11 government approvals, and are lawfully offered for sale. The suggested facts are not
12 true, and Plaintiff is informed and believes that Defendants do not believe them to be
13 true.

14 124. Plaintiff is informed and believes that Defendants willfully suppressed
15 and omitted the material facts concerning the safety concerns, approval status, and
16 illegality of TNS Product sales.

17 125. Defendants had a duty to disclose these material facts. The duty to
18 disclose arises from: (a) their superior and exclusive knowledge of these material
19 facts, which were not known or reasonably accessible to Plaintiff; (b) their active
20 concealment of these material facts, and/or (c) their marketing and sale of TNS
21 Products as skin rejuvenating cosmetics, which is likely to mislead consumers absent
22 full disclosure of the material facts at issue. In any event, product sellers must also
23 disclose safety concerns associated with the sale of consumer goods (particularly
24 drug products).

25 126. Defendants suppressed and omitted these material facts concerning the
26 safety concerns, approval status, and illegality of TNS Product sales with the intent
27 to induce Plaintiff and members of the Class to purchase TNS Products.
28

1 F. Award Plaintiff and the Class exemplary damages in such amount as
2 proven at trial, except that CLRA punitive damages will be requested after CLRA
3 notice;

4 G. Award Plaintiff and the Class reasonable attorneys' fees, costs, and pre-
5 and post-judgment interest; and

6 H. Award Plaintiff and the Class such other further and different relief as
7 the nature of the case may require or as may be determined to be just, equitable, and
8 proper by this Court.

9 **JURY TRIAL DEMAND**

10 Plaintiff, by counsel, requests a trial by jury on their legal claims, as set forth
11 herein.

12
13 DATED: March 19, 2014

**HAGENS BERMAN SOBOL
SHAPIRO LLP**

14
15 By 

Lee M. Gordon (174168)

16
17 lee@hbsslaw.com
301 N. Lake Avenue, Suite 203
18 Pasadena, CA 91101
Telephone: (213) 330-7150

19 Steve W. Berman (*Pro Hac Vice*
pending)

20 steve@hbsslaw.com
21 HAGENS BERMAN SOBOL
SHAPIRO LLP
22 1918 Eighth Avenue, Suite 3300
Seattle, WA 98101
23 Telephone: (206) 623-7292

24 *Attorneys for Plaintiff and the Proposed*
25 *Class*
26
27
28

1 STEVE W. BERMAN (*pro hac vice pending*)
steve@hbsslaw.com

2 HAGENS BERMAN SOBOL SHAPIRO LLP
1918 Eighth Avenue, Suite 3300
3 Seattle, WA 98101
Telephone: (206) 623-7292
4 Facsimile: (206) 623-0594

5 LEE M. GORDON (SBN 174168)
lee@hbsslaw.com

6 HAGENS BERMAN SOBOL SHAPIRO LLP
301 N. Lake Avenue, Suite 203
7 Pasadena, CA 91101
Telephone: (213) 330-7150
8 Facsimile: (213) 330-7152

9 *Attorneys for Plaintiffs and the Proposed Class*

10 UNITED STATES DISTRICT COURT
11 CENTRAL DISTRICT OF CALIFORNIA
12

13 Josette Ruhnke, an individual, *et al.*; on
14 behalf of herself and all others similarly
15 situated,

16 Plaintiff,

17 v.

18 SkinMedica, Inc., a Delaware
Corporation, and Allergan, Inc., a
19 Delaware Corporation,

20 Defendants.
21
22
23
24
25
26
27
28

No.

**DECLARATION OF JOSETTE
RUHNKE RE CLRA VENUE**

DECLARATION OF JOSETTE RUHNKE

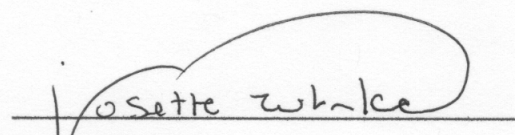
I, Josette Ruhnke, do hereby declare and state as follows:

1. I am a party plaintiff in *Josette Ruhnke, an individual, et al.; on behalf of herself and all others similarly situated, v. SkinMedica, Inc., a Delaware Corporation, and Allergan, Inc., a Delaware Corporation*. Pursuant to Cal. Civ. Code § 1780(d), I make this declaration in support of the Class Action Complaint and the claim therein for relief under Cal. Civ. Code § 1780(a). I have personal knowledge of the facts stated herein and, if necessary, could competently testify thereto.

2. This action for relief under Cal. Civ. Code § 1780(a) has been commenced in a district that is a proper place for trial of this action because: (i) Defendant Allergan, Inc. has its principal place of business in Orange County, California (within the Central District of California) and it does a substantial amount of business in this district; (ii) Defendant SkinMedica, Inc., an Allergan company, also conducts substantial business in this district; and (iii) I purchased one or more of the TNS Products at issue in Orange County, California (within this district).

This declaration is signed under penalty of perjury under the laws of the state of California and the United States this 18th day of March, 2014.

By:


Josette Ruhnke

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET**

| | |
|---|--|
| I. (a) PLAINTIFFS (Check box if you are representing yourself <input type="checkbox"/>) JOSETTE RUHNKE, an individual, et al; on behalf of herself and all others similarly situated, | DEFENDANTS (Check box if you are representing yourself <input type="checkbox"/>) SKINMEDICA, INC., a Delaware Corporation, and ALLERGAN, INC., a Delaware Corporation; |
| (b) County of Residence of First Listed Plaintiff <u>ORANGE COUNTY</u> <small>(EXCEPT IN U.S. PLAINTIFF CASES)</small> | County of Residence of First Listed Defendant _____ <small>(IN U.S. PLAINTIFF CASES ONLY)</small> |
| (c) Attorneys (Firm Name, Address and Telephone Number) If you are representing yourself, provide the same information. Lee M. Gordon (SBN 174168) HAGENS BERMAN SOBOL SHAPIRO LLP 301 N. Lake Ave., Suite 203 Pasadena, CA 91101 (213) 330-7150 | Attorneys (Firm Name, Address and Telephone Number) If you are representing yourself, provide the same information. |

| II. BASIS OF JURISDICTION (Place an X in one box only.) <div style="display: flex; justify-content: space-between;"> <div style="width:48%;"> <input type="checkbox"/> 1. U.S. Government Plaintiff </div> <div style="width:48%;"> <input type="checkbox"/> 3. Federal Question (U.S. Government Not a Party) </div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width:48%;"> <input type="checkbox"/> 2. U.S. Government Defendant </div> <div style="width:48%;"> <input checked="" type="checkbox"/> 4. Diversity (Indicate Citizenship of Parties in Item III) </div> </div> | III. CITIZENSHIP OF PRINCIPAL PARTIES -For Diversity Cases Only <small>(Place an X in one box for plaintiff and one for defendant)</small> <table style="width:100%;"> <tr> <th></th> <th>PTF</th> <th>DEF</th> <th></th> <th>PTF</th> <th>DEF</th> </tr> <tr> <td>Citizen of This State</td> <td><input checked="" type="checkbox"/> 1</td> <td><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business in this State</td> <td><input type="checkbox"/> 4</td> <td><input checked="" type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td><input type="checkbox"/> 2</td> <td><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business in Another State</td> <td><input type="checkbox"/> 5</td> <td><input type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td><input type="checkbox"/> 3</td> <td><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td><input type="checkbox"/> 6</td> <td><input type="checkbox"/> 6</td> </tr> </table> | | PTF | DEF | | PTF | DEF | Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in this State | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 | Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 | Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |
|---|---|----------------------------|---|----------------------------|---------------------------------------|-----|-----|-----------------------|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|--------------------------|----------------------------|----------------------------|---|----------------------------|----------------------------|---|----------------------------|----------------------------|----------------|----------------------------|----------------------------|
| | PTF | DEF | | PTF | DEF | | | | | | | | | | | | | | | | | | | | |
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in this State | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 | | | | | | | | | | | | | | | | | | | | |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 | | | | | | | | | | | | | | | | | | | | |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 | | | | | | | | | | | | | | | | | | | | |

IV. ORIGIN (Place an X in one box only.)

☒ 1. Original Proceeding

☐ 2. Removed from State Court

☐ 3. Remanded from Appellate Court

☐ 4. Reinstated or Reopened

☐ 5. Transferred from Another District (Specify)

☐ 6. Multi-District Litigation

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☒ Yes ☐ No (Check "Yes" only if demanded in complaint.)

CLASS ACTION under F.R.Cv.P. 23: ☒ Yes ☐ No **MONEY DEMANDED IN COMPLAINT:** \$ 5,000,000 +

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

Cal. Bus. & Prof. Code §17200, et seq.; Cal. Bus. & Prof. Code §1750, et seq.; Cal. Bus. & Prof. Code §17500, et seq.; Cal. Civ. Code §§1709-1710

VII. NATURE OF SUIT (Place an X in one box only.)

| OTHER STATUTES | CONTRACT | REAL PROPERTY CONT. | IMMIGRATION | PRISONER PETITIONS | PROPERTY RIGHTS |
|--|--|---|--|--|--|
| <input type="checkbox"/> 375 False Claims Act | <input type="checkbox"/> 110 Insurance | <input type="checkbox"/> 240 Torts to Land | <input type="checkbox"/> 462 Naturalization Application | Habeas Corpus: | <input type="checkbox"/> 820 Copyrights |
| <input type="checkbox"/> 400 State Reapportionment | <input type="checkbox"/> 120 Marine | <input type="checkbox"/> 245 Tort Product Liability | <input type="checkbox"/> 465 Other Immigration Actions | <input type="checkbox"/> 463 Alien Detainee | <input type="checkbox"/> 830 Patent |
| <input type="checkbox"/> 410 Antitrust | <input type="checkbox"/> 130 Miller Act | <input type="checkbox"/> 290 All Other Real Property | | <input type="checkbox"/> 510 Motions to Vacate Sentence | <input type="checkbox"/> 840 Trademark |
| <input type="checkbox"/> 430 Banks and Banking | <input type="checkbox"/> 140 Negotiable Instrument | | TORTS | <input type="checkbox"/> 530 General | SOCIAL SECURITY |
| <input type="checkbox"/> 450 Commerce/ICC Rates/Etc. | <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment | PERSONAL INJURY | <input checked="" type="checkbox"/> 370 Other Fraud | <input type="checkbox"/> 535 Death Penalty | <input type="checkbox"/> 861 HIA (1395ff) |
| <input type="checkbox"/> 460 Deportation | <input type="checkbox"/> 151 Medicare Act | <input type="checkbox"/> 310 Airplane | PERSONAL PROPERTY | Other: | <input type="checkbox"/> 862 Black Lung (923) |
| <input type="checkbox"/> 470 Racketeer Influenced & Corrupt Org. | <input type="checkbox"/> 152 Recovery of Defaulted Student Loan (Excl. Vet.) | <input type="checkbox"/> 315 Airplane Product Liability | <input type="checkbox"/> 371 Truth in Lending | <input type="checkbox"/> 540 Mandamus/Other | <input type="checkbox"/> 863 DIWC/DIWW (405 (g)) |
| <input type="checkbox"/> 480 Consumer Credit | <input type="checkbox"/> 153 Recovery of Overpayment of Vet. Benefits | <input type="checkbox"/> 320 Assault, Libel & Slander | <input type="checkbox"/> 380 Other Personal Property Damage | <input type="checkbox"/> 550 Civil Rights | <input type="checkbox"/> 864 SSID Title XVI |
| <input type="checkbox"/> 490 Cable/Sat TV | <input type="checkbox"/> 160 Stockholders' Suits | <input type="checkbox"/> 330 Fed. Employers' Liability | <input type="checkbox"/> 385 Property Damage Product Liability | <input type="checkbox"/> 555 Prison Condition | <input type="checkbox"/> 865 RSI (405 (g)) |
| <input type="checkbox"/> 850 Securities/Commodities/Exchange | <input type="checkbox"/> 190 Other Contract | <input type="checkbox"/> 340 Marine | BANKRUPTCY | <input type="checkbox"/> 560 Civil Detainee Conditions of Confinement | FEDERAL TAX SUITS |
| <input type="checkbox"/> 890 Other Statutory Actions | <input type="checkbox"/> 195 Contract Product Liability | <input type="checkbox"/> 345 Marine Product Liability | <input type="checkbox"/> 422 Appeal 28 USC 158 | FORFEITURE/PENALTY | <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) |
| <input type="checkbox"/> 891 Agricultural Acts | <input type="checkbox"/> 196 Franchise | <input type="checkbox"/> 350 Motor Vehicle | <input type="checkbox"/> 423 Withdrawal 28 USC 157 | <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 | <input type="checkbox"/> 871 IRS-Third Party 26 USC 7609 |
| <input type="checkbox"/> 893 Environmental Matters | REAL PROPERTY | <input type="checkbox"/> 355 Motor Vehicle Product Liability | CIVIL RIGHTS | <input type="checkbox"/> 690 Other | |
| <input type="checkbox"/> 895 Freedom of Info. Act | <input type="checkbox"/> 210 Land Condemnation | <input type="checkbox"/> 360 Other Personal Injury | <input type="checkbox"/> 440 Other Civil Rights | LABOR | |
| <input type="checkbox"/> 896 Arbitration | <input type="checkbox"/> 220 Foreclosure | <input type="checkbox"/> 362 Personal Injury-Med Malpractice | <input type="checkbox"/> 441 Voting | <input type="checkbox"/> 710 Fair Labor Standards Act | |
| <input type="checkbox"/> 899 Admin. Procedures Act/Review of Appeal of Agency Decision | <input type="checkbox"/> 230 Rent Lease & Ejectment | <input type="checkbox"/> 365 Personal Injury-Product Liability | <input type="checkbox"/> 442 Employment | <input type="checkbox"/> 720 Labor/Mgmt. Relations | |
| <input type="checkbox"/> 950 Constitutionality of State Statutes | | <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability | <input type="checkbox"/> 443 Housing/Accommodations | <input type="checkbox"/> 740 Railway Labor Act | |
| | | <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability | <input type="checkbox"/> 445 American with Disabilities-Employment | <input type="checkbox"/> 751 Family and Medical Leave Act | |
| | | | <input type="checkbox"/> 446 American with Disabilities-Other | <input type="checkbox"/> 790 Other Labor Litigation | |
| | | | <input type="checkbox"/> 448 Education | <input type="checkbox"/> 791 Employee Ret. Inc. Security Act | |

FOR OFFICE USE ONLY:

Case Number:

SACV14 - 00420 DOC (JPRx)

CV-71 (11/13)

CIVIL COVER SHEET

Page 1 of 3

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET**

VIII. VENUE: Your answers to the questions below will determine the division of the Court to which this case will most likely be initially assigned. This initial assignment is subject to change, in accordance with the Court's General Orders, upon review by the Court of your Complaint or Notice of Removal.

| | | | |
|---|---|--|------------------------------|
| Question A: Was this case removed from state court? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "no," go to Question B. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX. | STATE CASE WAS PENDING IN THE COUNTY OF: | | INITIAL DIVISION IN CACD IS: |
| | <input type="checkbox"/> Los Angeles | | Western |
| | <input type="checkbox"/> Ventura, Santa Barbara, or San Luis Obispo | | Western |
| | <input type="checkbox"/> Orange | | Southern |
| | <input type="checkbox"/> Riverside or San Bernardino | | Eastern |

| | | | |
|--|---|---|------------------------------|
| Question B: Is the United States, or one of its agencies or employees, a party to this action? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "no," go to Question C. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX. | If the United States, or one of its agencies or employees, is a party, is it: | | INITIAL DIVISION IN CACD IS: |
| | A PLAINTIFF? | A DEFENDANT? | |
| | Then check the box below for the county in which the majority of DEFENDANTS reside. | Then check the box below for the county in which the majority of PLAINTIFFS reside. | |
| | <input type="checkbox"/> Los Angeles | <input type="checkbox"/> Los Angeles | Western |
| | <input type="checkbox"/> Ventura, Santa Barbara, or San Luis Obispo | <input type="checkbox"/> Ventura, Santa Barbara, or San Luis Obispo | Western |
| | <input type="checkbox"/> Orange | <input type="checkbox"/> Orange | Southern |
| | <input type="checkbox"/> Riverside or San Bernardino | <input type="checkbox"/> Riverside or San Bernardino | Eastern |
| <input type="checkbox"/> Other | <input type="checkbox"/> Other | Western | |

| Question C: Location of plaintiffs, defendants, and claims? (Make only one selection per row) | A. Los Angeles County | B. Ventura, Santa Barbara, or San Luis Obispo Counties | C. Orange County | D. Riverside or San Bernardino Counties | E. Outside the Central District of California | F. Other |
|--|--------------------------|---|-------------------------------------|--|--|--------------------------|
| Indicate the location in which a majority of plaintiffs reside: | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Indicate the location in which a majority of defendants reside: | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Indicate the location in which a majority of claims arose: | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | |
|--|---|
| C.1. Is either of the following true? If so, check the one that applies: <input checked="" type="checkbox"/> 2 or more answers in Column C <input type="checkbox"/> only 1 answer in Column C and no answers in Column D Your case will initially be assigned to the SOUTHERN DIVISION. Enter "Southern" in response to Question D, below. If none applies, answer question C2 to the right. → | C.2. Is either of the following true? If so, check the one that applies: <input type="checkbox"/> 2 or more answers in Column D <input type="checkbox"/> only 1 answer in Column D and no answers in Column C Your case will initially be assigned to the EASTERN DIVISION. Enter "Eastern" in response to Question D, below. If none applies, go to the box below. ↓ |
| Your case will initially be assigned to the WESTERN DIVISION. Enter "Western" in response to Question D below. | |

| | |
|---|--------------------------|
| Question D: Initial Division? | INITIAL DIVISION IN CACD |
| Enter the initial division determined by Question A, B, or C above: → | SOUTHERN |

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET**

IX(a). IDENTICAL CASES: Has this action been previously filed **in this court** and dismissed, remanded or closed? ☒ NO ☐ YES

If yes, list case number(s): _____

IX(b). RELATED CASES: Have any cases been previously filed **in this court** that are related to the present case? ☒ NO ☐ YES

If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply)

- ☐ A. Arise from the same or closely related transactions, happenings, or events; or
- ☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
- ☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
- ☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

**X. SIGNATURE OF ATTORNEY
(OR SELF-REPRESENTED LITIGANT):** _____

DATE: 3/19/2014

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet).

Key to Statistical codes relating to Social Security Cases:

| Nature of Suit Code | Abbreviation | Substantive Statement of Cause of Action |
|---------------------|--------------|--|
| 861 | HIA | All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b)) |
| 862 | BL | All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923) |
| 863 | DIWC | All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405 (g)) |
| 863 | DIWW | All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g)) |
| 864 | SSID | All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended. |
| 865 | RSI | All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g)) |

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES JUDGES

This case has been assigned to District Judge David O. Carter and the assigned Magistrate Judge is Jean P. Rosenbluth.

The case number on all documents filed with the Court should read as follows:

SACV14-00420 DOC (JPRx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge.

Clerk, U. S. District Court

March 19, 2014

Date

By D. Lagman
Deputy Clerk

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

☐ Western Division
312 N. Spring Street, G-8
Los Angeles, CA 90012

☒ Southern Division
411 West Fourth St., Ste 1053
Santa Ana, CA 92701

☐ Eastern Division
3470 Twelfth Street, Room 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.